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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
FMC-1012US	

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Application Number	Filed
10/521,886	July 5, 2005
First Named Inventor	
Robert Kopesky	
Art Unit	**Examiner**
1609	Layla D. Bland

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☑ attorney or agent of record. Registration number 32,024

☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

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Typed or printed name

215-599-0600
Telephone number

February 29, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Robert Kopesky et al.	: Confirmation No.: 8844
U. S. Patent Application No.: 10/521,886	: Group Art Unit: 1609
Filed: July 5, 2005	: Examiner: Layla D. Bland
For: PRODUCTION OF MICROCRYSTALLINE CELLULOSE	: Atty. Docket No.: FMC-1012US

Mail Stop AF, Director for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 4-7 have been rejected under 35 U.S.C. §112, second paragraph, on the basis that, "at least about" is a relative term that renders these claims indefinite. MPEP §2173.05(b) provides that,

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Thus, use of relative terminology does not automatically render the claim indefinite and the Examiner must justify why, in the context of the present application, the term, "at least about" renders the claim indefinite. The only basis provided by the Examiner is the allegation that, "The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree..." Final Rejection, p. 3, ll. 2-3. 35 U.S.C. 112 does not require that terms be defined by the claim and the specification provides information on the meaning of the terminology "at least about."

Page 8, l. 4 of the specification says the reaction mixture will heat to "at least about 40°C." Page 8, line 12 of the specification gives a preferred temperature range of "about 50 to 110°C." "At least about 40°C" must be different from "about 50°C" or "about 50°C" would not have been mentioned as a preferred embodiment of "at least about 40°C". Thus, the specification indicates that "about" means at most ± 5°C since otherwise "about 40°C" would overlap with "about 50°C". The Examiner erroneously disregards this on the basis that, "A preferred example is not a clear definition." See Final Rejection, p. 3, l. 10. 35 U.S.C. §112 does not require that the specification provide a clear definition of a term, but only that the term can be interpreted with a reasonable degree of particularity.

The Examiner asserts that *Amgen, Inc. v. Chugai*, 927 F.2d 1200, 1218, 18 USPQ2d 1016 (Fed. Cir. 1991) mandates a determination that "at least about" is indefinite. This one case was clearly a highly exceptional case since 68,946 U.S. patents have issued just since 1976 employing the phrase "at least about" in the claims showing that in at least 68,946 circumstances, this terminology satisfied 35 U.S.C. 112. Also, two other cases, *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446, 7 USPQ2d 1191, 11999 (Fed. Cir. 1988) ("at least about") and *W.L. Gore & Associates, Inc. v. Garlock,*

Inc., 842 F.2d 1275, 6 USPQ2d 1277 (Fed. Cir. 1988) ("exceeding about") held that essentially the same terminology satisfied 35 U.S.C. 112. *Amgen* referenced *W.L. Gore & Associates*, indicating that,

> In arriving at this conclusion, we caution that our holding that the term "about" renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims. It may be acceptable in appropriate fact situations, *e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 U.S.P.Q. (BNA) 303, 316 (Fed. Cir. 1983) ("use of 'stretching . . . at a rate exceeding about 10% per second' in the claims is not indefinite"), even though it is not here.

927 F.2d at 1218. Thus, even *Amgen* cautioned that it should not rule out use of the term, "about" in patent claims, as the Examiner suggests. The present case is not an exceedingly exceptional case as in *Amgen* since the facts of *Amgen* were significantly different. *Amgen* stated,

> The court found the "addition of the word 'about' seems to constitute an effort to recapture . . . a mean activity somewhere between 120,000, which the patent examiner found was anticipated by the prior art, and [the] 160,000 IU/AU" claims which were previously allowed. Because "the term 'about' 160,000 gives no hint as to which mean value between the Miyake et al. value of 128,620 and the mean specific activity level of 160,000 constitutes infringement," the court held the "at least about" claims to be invalid for indefiniteness. 13 U.S.P.Q.2d at 1787-88.

927 F.2d at 1218. In the present case, "at least about" was not added by amendment and there has been no effort to recapture subject matter using this terminology. Finally, *Amgen* said,

> This holding was further supported by the fact that nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term "about," and by the fact that no expert testified as to a definite meaning for the term in the context of the prior art.

927 F.2d at 1218. As discussed above, the present specification provides an indication as to what range of temperature is covered by the term, "at least about", contrary to the situation of *Amgen*. Finally, in *Amgen* there was prior art that met every limitation of the claim except the limitation containing "at least about." In the present case, the Examiner admits that Hanna completely lacks a teaching of a process for producing microcrystalline cellulose using an active oxygen compound (Final Rejection, p. 5, ll. 7-8). The missing limitation is not the limitation containing "at least about" as it was in *Amgen*. Accordingly, the Examiner has not met her burden of establishing a *prima facie* case of indefiniteness.

Claims 1-7, 20, 22-24, 26 and 28 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Pat. no. 6,228,232 B1 (Hanna), in view of WO 01/02441 A1 (Schaible) and U.S. Pat. no. 6,392,034 B1 (Trusovs). Claims 18-21, 25-27 and 29-31 stand rejected under 35 U.S.C. §103(a) as unpatentable over the same references and further in view of U.S. Pat. no. 5,192,569 (McGinley).

The invention of claim 1 is a process for producing microcrystalline cellulose. A reaction mixture comprising a cellulose material, an active oxygen compound and water, is subjected to a high shear treatment at elevated temperature for a time effective to depolymerize the cellulose material. This is an efficient, one-step process for the production of microcrystalline cellulose.

Hanna discloses a process for producing microcrystalline cellulose by subjecting a reaction mixture of cellulose material, water and acid to reactive extrusion at an extruder barrel temperature of 80-200°C. The Examiner admits that Hanna does not disclose using an active oxygen compound (Final Rejection, p. 5, ll. 7-8). Schaible teaches a process for producing microcrystalline cellulose by hydrolyzing pulp with active oxygen. The starting material of Schaible is simultaneously hydrolyzed and bleached to obtain a microcrystalline cellulose product. (p. 2, ll. 20-24). Trusovs teaches a method of producing microcrystalline cellulose by treating cellulose with an alkaline solution at 20-100°C to form an alkaline suspension and adding a peroxide solution to reduce the suspension viscosity.

The Examiner concludes that it would have been obvious to use the reactive extrusion process of Hanna with hydrogen peroxide to produce microcrystalline cellulose (Final Rejection, p. 5, ll. 4-6) in view of Schaible or Trusovs. The Examiner alleges two motivations to combine the teachings of the cited references: (1) it would be obvious to modify Schaible to employ the extruder method of Hanna to achieve a shorter reaction time, and (2) it would be obvious to use the hydrogen peroxide of Schaible or Trusovs for hydrolysis since it also bleaches the material at the same time and thus, according to the Examiner, there would be no need for a separate bleaching step if this were done.

With respect to motivation (1), Hanna teaches that the extruder method has a shorter reaction time than conventional batch processes for acid hydrolysis of cellulose (col. 1, ll. 33-40 and col. 2, ll. 5-20), but does not disclose the reaction time. All that is known from Hanna is that relative to a batch acid hydrolysis process, the acid hydrolysis method of Hanna has a shorter reaction time. Neither Schaible nor Trusovs relate to the conventional batch processes for acid hydrolysis of cellulose referred to in Hanna. Thus, the skilled person cannot determine from Hanna whether the extruder method of Hanna would produce a shorter reaction time than in Schaible or Trusovs. Accordingly, obtaining a reduction in reaction time cannot be a motivation for a skilled person to modify Schaible since the Examiner's alleged reduction in reaction time is pure speculation.

Further, the facts contradict the Examiner's position. The Schaible reaction is performed at high temperature (e.g. 100°C) (p. 7, ll. 20-22 and examples of Schaible). Thus, the method of Schaible differs from the conventional processes to which Hanna compares its reaction time because (1) the Schaible process is not a conventional batch acid hydrolysis reaction, and (2) Schaible already operates at high temperature. Therefore, use of the extruder method of Hanna would not necessarily raise the temperature already employed by Schaible, as the Examiner assumes. Hanna specifies that the temperature during the acid hydrolysis step should be 80-200°C on the extruder barrel (col. 3, lines 60-63), which encompasses 100°C as used in Schaible. Thus, use of the extruder method of Hanna may result in a reduction of the reaction temperature (e.g. from 100°C of Schaible to the 80°C on the extruder barrel of Hanna) rather than increase in reaction temperature as the Examiner assumes.

Hanna nowhere teaches that increasing pressure will decrease reaction time. All of the reactions in Hanna are run at the same pressure. It is quite possible that use of a high temperature is solely responsible for the reduction in reaction time described in Hanna and that changes in pressure do not even affect the reaction time. Clearly, Hanna does not support a conclusion that increased pressure would reduce the reaction time of the method of either Schaible or Trusovs

The Examiner's alleged motivation (2) for combining the references is also unsupported since the references provide insufficient information to conclude that "there would be no need for a separate bleaching step." In fact, the record indicates that there would almost always be a need for a separate bleaching step, contrary to the Examiner's position. First, some of the starting materials contemplated for use by Hanna (e.g. pure cellulose) do not even require bleaching. Thus, if pure cellulose were the starting material, the Examiner's alleged motivation (2) for combining the references would not apply since there would already be no need for a separate bleaching step and thus, in this circumstance, there would be no reason to use hydrogen peroxide for bleaching. The Examiner concedes that the need for bleaching is dependent on the starting material used at p. 9, ll. 4-7 of the Final Rejection.

The Examiner assumes that the subsequent bleaching step of Hanna can be eliminated by combining the extruder method of Hanna with the method of Schaible. However, the Examiner cites no basis in the cited references for this assumption. A close review of the teachings of Schaible leads to the opposite conclusion that in nearly all cases, a subsequent bleaching step will still be required even if an active oxygen compound is employed. Schaible compares its products to the color lightness of two commercial microcrystalline cellulose products, namely, Emcocel® 50M and Emcocel® 90M in Table 1 of Example 1 on page 8. These commercial products had lightness values (L*) of 98.3 and 97.87, respectively. Examples 1-7, 9-10 and 12-15 and 17 of Schaible all employed an active oxygen compound, yet, of all of these examples, only Example 1 of Schaible achieved a lightness value equal to or greater than the commercial microcrystalline cellulose products which Schaible uses as a comparative standard. All of the remaining examples 2-7, 9-10 and 12-15 and 17 of Schaible resulted in lightness values (L*) inferior to the lightness values of the commercial microcrystalline cellulose products. From this, a skilled person would conclude that in nearly all circumstances, an additional bleaching step would be required after the process of Schaible in order to provide products having lightness values comparable to the existing commercial microcrystalline cellulose products which Schaible uses as a reference standard. Accordingly, from Schaible there is no reasonable expectation of successfully eliminating the subsequent bleaching step by using active oxygen as the Examiner suggests. Thus, the second motivation relied on by the Examiner also fails since it is contrary to the clear teachings of Schaible.

The Examiner also draws several conclusions which rely on the alleged interchangeability of the acid hydrolysis step of Hanna with the process of Schaible. Hanna employs acid hydrolysis to de-polymerize wood pulp by cleaving the cellulose chains in the amorphous regions but leaving crystallites hydrogen bonded to each other. This is not the chemical equivalent of treatment with an active oxygen compound as in Schaible. The present specification teaches that treatment with an active oxygen compound provides different effects on the cellulose that appear to be independent of acid hydrolysis. See e.g. p. 9, ll. 10-16 of the specification. Trusovs also teaches that treatment with peroxide causes some oxidation of the cellulose to occur. See col. 2, ll. 49-53 of Trusovs. A skilled person would therefore not consider an active oxygen treatment to be interchangeable with the acid hydrolysis step of Hanna since active oxygen treatment results in a different chemical reaction than acid hydrolysis and thus will provide different reaction products. As a result, the skilled person would expect that the properties of the cellulose material would be materially changed if the active oxygen treatment were added to, or substituted for, the acid hydrolysis reaction of Hanna. This would lead a skilled person to conclude that the active oxygen treatment should not be substituted for, or added to, the acid hydrolysis step of Hanna since the effect of the additional oxidation reaction on the properties of the resultant microcrystalline cellulose of Hanna for use to make tablets (see e.g. col. 6, lines 15-22 of Hanna), would be unpredictable. A skilled person desiring to make tablets (which are subject to FDA approval) would certainly avoid implementation of steps that would produce unpredictable chemical products since the presence of such products could jeopardize the marketability of the tablet.

Trusovs entire purpose is to avoid use of an acid hydrolysis method. See e.g. col. 1, lines 34-38 and col. 2, lines 10-15 of Trusovs. A skilled person would not combine Trusovs with either Hanna or Schaible since both employ acid hydrolysis methods which Trusovs desires to avoid. Another object of Trusovs is to provide a method for producing MCC which does not involve high temperature or high pressure (col. 2, lines 22-24 and 38-41). Thus, a skilled person also would not combine Trusovs with Hanna or Schaible since Hanna and Schaible both employ high temperatures and Hanna also employs high pressure.

McGinley et al. does not cure the defects of the primary references discussed above. Accordingly the same reasons given above apply to the rejection of claims 18-21, 25-27 and 29-31 due to their dependence on claim 1. Withdrawal of the rejections is requested.

Date: February 29, 2008
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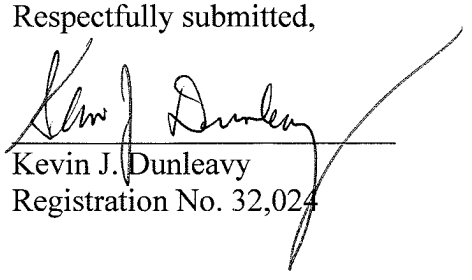
Respectfully submitted,



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